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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,689	08/14/2006	Paul S. Liu	251611	7386

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EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
02/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,689	LIU ET AL.	
	Examiner	Art Unit	
	Bruck Kifle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,16-18,21,24,27,30,31,37,40,48-50,57,58,62,68-70 and 81-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,16-18,21,24,27,30,31,37,40,48-50,57,58,62,68-70 and 81-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-4, 16-18, 21, 24, 27, 30, 31, 37, 40, 48-50, 57, 58, 62, 68-70 and 81-95 are pending in this application.

Claim Rejections - 35 USC § 112

Claims 1-4, 16-18, 21, 24, 27, 30, 31, 37, 40, 48-50, 57, 58, 62, 68-70 and 81-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
i) X and Y are defined as "a substituent selected from the group consisting of an OH, an ether, a silyl ether, a trialkyl silyl ether, an ester, a carbonate, a carbamate, a thiocarbamate, a cyclic carbamate, a cyclic thiocarbamate, an acetate, SH, a sulfide, a sulphoxide, a sulphone, a sulphite, a bisulphite, a sulphonamide, an amine, an amide, an azido, a cyano, a halo, a triphenylphosphonium, a silyl, a trialkyl silyl, an amino acid-derived group, and a phosphorus-containing group."

Most of these are not radicals but compounds with no points of attachments. Take, for example, ether, which is a compound of the general formula R-O-R'. It is unclear what Applicants intention is (is an alkoxyalkyl group or a cycloalkyloxy or heteroaryloxyalkyl intended?) Appropriate correction to the intended radicals is required.

The triphenylphoshonium group needs to have a counter ion present when it is attached to the rest of the molecule.

The nature of the "amino acid-derived" group is not known. One cannot say which amino acids (Natural? Alpha? Beta? Famous 20?) are intended and how the group is derived therefrom? To what degree is it derivatized and when is a group no longer considered an amino acid-derived group?

The nature of the "phosphorous-containing group" is also unclear. One skilled in the art cannot say which group is embraced by this phrase.

ii) In the definition of Z the nature of the heteroatom contained in the alkyl, alkenyl or alkynyl is not known.

iii) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not.

iv) The term "heterocyclic" is indefinite because it is not known how many atoms make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended.

v) Regarding claims 49, 89 and 94, it is unclear which cells' growth is inhibited and what is accomplished thereby.

Claims 49, 50, 57, 58, 89, 90, 94 and 95 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claims 49, 50, 89 and 94, the how to use portion of the statute has not been addressed. This means that Applicants must teach the skilled practitioner, in this case a physician, how to treat a given subject. The physician clearly must know what disease and what symptoms are to be treated. In this case, Applicants have not provided what is being treated by claims 49, 50, 89 and 94, who the subject is, how one can identify said subject (i.e. how one can identify a subject in need), given no specific dose, given no specific dosing regimen, given no

specific route of administration, and do not specify what diseases or symptom they intend to treat.

These claims read on inhibiting the growth of a cell *in vitro* or inhibiting the growth of a cell in mammals with normal cell. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' inhibitor falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967). As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. Genentech Inc. v. Novo Nordisk 42 USPQ2d 1001.

Claims 57, 58, 90 and 95 are drawn to a method of treating a viral, parasitic or bacterial infection. The claim is directed to all viral infections. The claimed utility is an extraordinary one in that it asserts that administration of these compounds is effective against the full complex of viral, parasitic or bacterial infections.

Despite the colossal amount of research, since viruses were first identified as infective agents no one has found an agent that is effective against all viruses. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs. Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The situation with viruses may be contrasted with that for bacterial infections. Certain agents, especially tetracycline and β-lactams are routinely found effective against a broad range of bacteria species. Thus, antibiotic activity against a single gram-positive species means that activity against all Gram-positive bacteria. The clinician uses this knowledge to prescribe penicillin without determining which bacterium is responsible for the infection.

A far different situation prevails for viruses. Commonly an antiviral agent will be effective against a single species but not effective against other viruses in the same genus. What few antiviral agents exist are effective against only a limited range of viruses. Amantadine has some effect on Influenza A but is ineffective against Influenza B or C. Foscavir is effective against HSV-1 and HSV-2 but ineffective against VZV. All three viruses are herpes viruses. Acyclovir, the most widely used agent for herpes is not effective against virus corneal epithelial

herpes. AZT, part of the widely used treatment for HIV is not effective against DNA containing viruses. 5-FU, applied topically is effective against the human papilloma virus but has no effect against RNA viruses systemically or topically. Rabies has been known for hundreds of years. It is treated with a specific vaccine, which of course is ineffective against any other species of virus. No small molecule treatment of rabies is known. This lack of general efficacy in the antiviral arts means that a clinician is required to identify the species of viruses causing the disease before beginning treatment. This is in sharp contrast to the situation with bacteria.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is 571-272-0668. The examiner can normally be reached on Mondays-Fridays from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruck Kifle/
Primary Examiner
Art Unit 1624

BK
February 12, 2008